LAFAYETTE & KUMAGAI LLP
GARY T. LAFAYETTE (SBN 088666)
Email: glafayette@lkclaw.com
100 Spear Street, Suite 600
San Francisco, California 94105
Telephone: (415) 357-4600
Facsimile: (415) 357-4605

PATTERSON BELKNAP WEBB & TYLER LLP
STEVEN A. ZALESIN (admitted *pro hac vice*)
Email: sazalesin@pbwt.com
TRAVIS J. TU (admitted *pro hac vice*)
Email: tjtu@pbwt.com
1133 Avenue of the Americas
New York, New York 10036-6710
Telephone: (212) 336-2000
Facsimile: (212) 336-2222

Attorneys for Defendants
ODWALLA, INC. and THE COCA-COLA COMPANY

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ROBIN REESE, individually and on behalf of all others similarly situated,

Plaintiff,

vs.

ODWALLA, INC. and THE COCA-COLA COMPANY,

Defendants.

Case No. 3:13-CV-00947-YGR

NOTICE OF MOTION AND MOTION; MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, TO STRIKE PORTIONS OF PLAINTIFF'S COMPLAINT

Judge: Hon. Yvonne Gonzalez Rogers

Complaint Filed: March 1, 2013
Hearing Date: July 23, 2013
Hearing Time: 2 P.M.
Courtroom: 5

NOTICE OF MOTION AND MOTION

TO PLAINTIFF AND PLAINTIFF'S ATTORNEY OF RECORD:

PLEASE TAKE NOTICE THAT on July 23, 2013, at 2:00 p.m., or as soon thereafter as this may be heard, in Courtroom 5 of this Court, located at 1301 Clay Street, Oakland, CA 94612, before the Honorable Yvonne Gonzalez Rogers, defendants the Coca-Cola Company and Odwalla, Inc. (collectively, "Odwalla") will and hereby do move the Court for an order dismissing plaintiff's Complaint and each claim therein filed by plaintiff Robin Reese.

This motion is made pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(f), and is based on the following grounds:

1. Plaintiff has failed to state a claim because she has failed to allege a violation of California's Sherman Food, Drug and Cosmetic Law, Cal. Health & Saf. Code §§ 109875 *et seq*.

2. Plaintiff's claims are expressly and impliedly preempted by the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, or, at minimum, present issues that should be left to the FDA under the doctrine of primary jurisdiction.

3. Plaintiff's nationwide class allegations should be stricken from the Complaint.

4. Plaintiff's allegations regarding Fanta Zero Orange Soda are impertinent to this matter and should be stricken from the Complaint.

This motion is based on this notice of motion, the accompanying statement of issues to be decided, the accompanying memorandum of points and authorities, all pleadings and documents on file in this case, and on such other written and oral argument as may be presented to the Court.

DATE: June 3, 2013

PATTERSON BELKNAP WEBB & TYLER LLP
/s/ Steven A. Zalesin
Steven A. Zalesin (admitted *pro hac vice*)
Travis J. Tu (admitted *pro hac vice*)

Gary T. Lafayette
LAFAYETTE & KUMAGAI LLP

Attorneys for Defendants

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STATEMENT OF ISSUES

1. Does California law authorize a private party to enforce a non-final, non-binding draft FDA guidance on food labeling when, according to the plain text of the applicable statute, California law incorporates only final, binding FDA regulations?

2. Are Plaintiff's state-law claims, which seek to impose food labeling requirements that FDA has considered but thus far chosen not to impose, expressly and impliedly preempted by the federal Food Drug and Cosmetic Act?

3. Should Plaintiff's claims be dismissed on primary jurisdiction grounds when FDA has already initiated a process to determine whether "evaporated cane juice" is an appropriate common and usual name, and that process is ongoing?

4. Should Plaintiff's nationwide class allegations be stricken when the California Supreme Court has held that California's unique consumer protection regime does not govern events that occur outside the state, and it would clearly frustrate the laws and public policies of other States to apply California law extraterritorially in this case?

INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiff alleges that labels for certain Odwalla® brand beverages and snack bars violate the federal Food Drug and Cosmetic Act ("FDCA") and California law because they identify evaporated cane juice in the products' ingredient lists. According to Plaintiff, the term "evaporated cane juice" ("ECJ") is unlawful because it "runs afoul" of a non-binding, draft guidance published by the U.S. Food and Drug Administration ("FDA") in 2009, which stated that FDA is preliminarily of the view that this sweetener should be identified by a different name that does not use the word "juice." *See* "*Guidance for Industry: Ingredients Declared as Evaporated Cane Juice*" (hereinafter "2009 Draft Guidance").[1]

For multiple reasons, Plaintiff's claims lack merit and must be dismissed. *First*, Plaintiff bases her claims on California's Sherman Law, which makes FDCA requirements and FDA regulations concerning food labels the law of that state. The Sherman Law, however, only incorporates into California law final, binding requirements of federal law. FDA's 2009 Draft Guidance is not a final, binding requirement; it is only a draft "Level 1" guidance—the least formal type of Agency document. By law, a draft "Level 1" guidance creates no legally enforceable requirements and is not binding on FDA or the public. Plaintiff therefore cannot use California law to enforce it.

Second, Plaintiff is expressly preempted from using state law to impose requirements for food and beverage labels that differ from the requirements of federal law. In 1990, Congress amended the FDCA to include an express preemption clause, which preempts all state-law requirements for food labeling that are "not identical" to federal law. At present, federal law does not prohibit manufacturers from labeling ECJ by that name, and ECJ is labeled as an ingredient on hundreds of foods and beverages sold throughout the country. Moreover, in the

[1] A copy of the 2009 Draft Guidance is attached as Exhibit A to Odwalla's Request for Judicial Notice (hereinafter "RJN"). Regulatory documents are properly subject to judicial notice on a motion to dismiss. *See Hansen Beverage Co. v. Innovation Ventures, LLC*, 2009 U.S. Dist. LEXIS 127605, at *6-7 (S.D. Cal. Dec. 22, 2009). "This includes public records and government documents available from reliable sources on the Internet." *United States ex rel. Dingle v. BioPort Corp*., 270 F. Supp. 2d 968, 972 (W.D. Mich. 2003), *aff'd*, 388 F.3d 209 (6th Cir. 2004).

years since FDA published the 2009 Draft Guidance, the Agency has received dozens of comments critical of the proposal, and has taken no steps to convert the draft guidance into a binding legal requirement. Plaintiff is expressly preempted from using California law to require that ECJ be labeled by a different name when federal law does not—and, indeed, might never—impose that requirement.

Third, although the FDCA and California law contain an "identical" requirement that manufacturers must list products' ingredients by an appropriate common and usual name, Plaintiff cannot fall back on this general requirement to circumvent the FDCA's preemption clause. Courts have consistently rejected attempts to use the general requirements of the FDCA to bypass FDA's approach to specific labeling issues. FDA has specifically considered the issue of ECJ, and so far has chosen not to establish by regulation a common and usual name for this sweetener. Plaintiff is expressly preempted from asking this Court or a jury to interpret and apply California's general common and usual name requirement in a manner that FDA has not under federal law. Additionally, Plaintiff is barred by the doctrines of implied preemption and primary jurisdiction from attempting to use the general common and usual name requirement to short-circuit FDA's draft guidance process and convert the 2009 Draft Guidance into a binding legal requirement when FDA has not done so.

Fourth, and at a minimum, the Court should strike Plaintiff's nationwide class allegations. California law is unique insofar as it purports to allow private plaintiffs to sue to enforce FDCA requirements under state law. While some states have enacted "mini-FDCA" statutes of their own, legislators in those states have made a deliberate policy choice not to permit private enforcement or remedies. Where, as here, it would frustrate the policy choices of other states to project the purported requirements of California law beyond the state's borders, a nationwide class is clearly inappropriate.

For these and other reasons set forth below, Plaintiff's claims must be dismissed with prejudice and/or stricken in substantial part.

BACKGROUND

A. The Products

Odwalla sells more than 50 varieties of Odwalla beverages and bars. Odwalla beverages come in flavors ranging from apple and carrot to "Mango Tango" and "Pomegranate Limeade." Odwalla bars are also available in a wide variety of flavors such as Banana Nut, Chocolate Peanut Butter, and Lemon Ginger. Depending on the type of beverage or bar, Odwalla uses different sweeteners to achieve the desired taste or nutritional profile. Some Odwalla products contain naturally sweet fruit juice with no added sugars. Others contain one or more sweetening ingredients such as brown rice syrup, vegetable glycerin, cane syrup, or ECJ.

All Odwalla products are labeled with a Nutrition Facts panel that provides consumers with detailed information about the products' nutrients and calorie content. In accordance with federal law, the Nutrition Facts panel prominently discloses the total grams of "sugars" in each product per serving, and a list of the products' ingredients appear on the label. Odwalla products sweetened with ECJ list this ingredient on their labels, and their Nutrition Facts panels include ECJ in the total amount of sugars disclosed.

B. Plaintiff's Allegations

Plaintiff is a California resident who alleges that she has purchased Odwalla products sweetened with ECJ. Specifically, Plaintiff alleges that she purchased two Odwalla beverages (Strawberry Protein Monster™ Shake and Quencher Pomegranate Limeade) and two Odwalla bars (Chocolate Almond Coconut and White Chocolate Macadamia) (collectively the "Products").[2] (Compl. ¶75.)

Plaintiff does not allege that Odwalla concealed from her the presence of ECJ. On the contrary, Plaintiff alleges that she thoroughly reviewed the Products' labels, noted the presence of "evaporated cane juice" in the ingredients list, and relied on that fact in making her purchasing

[2] Copies of the labels for these products are attached as Exhibits P-S to Odwalla's accompanying RJN. The Court may take judicial notice of the Products' labels because they are referenced in the Complaint. *See McKinniss v. Sunny Delight Beverages Co.*, 2007 U.S. Dist. LEXIS 96108, at *9-10 n.1 (C.D. Cal. Sept. 4, 2007).

decisions. (*Id.* ¶76.) According to Plaintiff, however, ECJ is an "unlawful and unauthorized" name, and the Products accordingly were "misbranded" in violation of the FDCA and California's Sherman Law. (*Id.* ¶79.) Had she known that it is unlawful to identify ECJ by that name, Plaintiff alleges, she would not have purchased the Products or would have paid less.

Plaintiff bases her allegation on FDA's 2009 Draft Guidance concerning ECJ. (*Id.* ¶41.) According to the Complaint, the 2009 Draft Guidance "advised the industry that the term 'Evaporated Cane Juice' is unlawful," but Odwalla's labels "continue to run afoul" of this requirement. (*Id.* ¶47.) Based on these allegations, Plaintiff asserts statutory claims under California's Unfair Competition Law ("UCL") (Cal. Bus. & Prof. Code § 17200 et seq.) (Counts I-III), California's False Advertising Law ("FAL") (Cal. Bus. & Prof. Code § 17500 et seq.) (Counts IV-V), California's Consumer Legal Remedies Act ("CLRA") (Cal. Civ. Code § 1750 et seq.) (Count VI), and a common law claim for unjust enrichment/quasi-contract (Count VII). Plaintiff asserts these claims on behalf of herself and a putative nationwide class of consumers who have purchased Odwalla products labeled with ECJ in the past four years. (*Id.* ¶82.)

C. Statutory and Regulatory Framework

1. The FDCA Expressly Preempts Non-Identical State Requirements

Congress enacted the FDCA in 1938, creating "a comprehensive federal scheme for the regulation of food." *Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111, 1117 (C.D. Cal. 2010). The FDCA gave FDA broad authority to "promote honesty and fair dealing in the interest of consumers." 21 U.S.C. § 341; *see also* 21 U.S.C. § 371 (authorizing FDA to "promulgate regulations for the efficient enforcement" of the FDCA). However, FDA did not comprehensively regulate the labeling of foods and beverages prior to 1990.

Between 1938 and 1990, the market for food and beverages in the U.S. underwent radical transformation. Mass-produced packaged foods and beverages became the norm, and Congress recognized that national labeling standards were overdue. *See generally* Institute of Medicine, Food Labeling: Toward National Uniformity, National Academy Press (Washington, D.C.

1992), at 35-54. Congress responded with the Nutrition Labeling and Education Act of 1990 ("NLEA"), which expressly expanded FDA's authority over food and beverage labeling. *Id.*

The NLEA was intended to "make sense of the confusing array of nutrition labels that confront all consumers every time they enter the supermarket," 136 Cong. Rec. H5836, H5840 (daily ed. July 30, 1990) (statement of Rep. Waxman), "while providing the industry with uniformity of law . . . that will permit them to conduct their business of food distribution in an efficient and cost-effective manner." *Id.* at H5843 (statement of Rep. Madigan). Congress sought to achieve these goals in two related ways. First, the NLEA amended the FDCA to standardize, *inter alia*, "the form and substance of ingredient labeling on packages" nationwide. *Briseno v. Conagra Foods, Inc.*, 2011 U.S. Dist. LEXIS 154750, at *12-13 (C.D. Cal. Nov. 23, 2011). Second, the NLEA provided that federal law would expressly "preempt non-identical [state-law] requirements in the field of food labeling." *Turek v. Gen. Mills, Inc.*, 754 F. Supp. 2d 956, 958 (N.D. Ill. 2010), *aff'd*, 662 F.3d 423 (7th Cir. 2011).

The NLEA's express preemption clause displaced states from their traditional role in regulating food and beverage labeling by mandating that:

> no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement for the labeling of food of the type required by . . . [among others, Section 343(i)] . . . that is ***not identical to*** the requirement of such section.

21 U.S.C. § 343-1(a) (emphasis added). A state requirement is "not identical to" federal requirements — and thus, is preempted —if it "directly or indirectly" imposes labeling obligations that are "***not imposed by or contained in*** the applicable [federal] provision (including any implementing regulation)" or that "***[d]iffer from those specifically imposed or contained in*** the applicable provision." 21 C.F.R. § 100.1(c)(4) (emphasis added).

2. FDA Has Exclusive Authority to Enforce the FDCA

The FDCA contains no private right of action. 21 U.S.C. § 337(a). In fact, the statute "leaves no doubt that it is the Federal Government rather than private litigants who are

authorized to file suit for noncompliance." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).[3]

FDA's exclusive enforcement authority has "major advantages." *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995). FDA has substantial "expertise" that it brings to bear; has the "ability to solicit comment from appropriate sources"; provides "direct representation of the public interest"; and can maintain a "unitary enforcement policy" for the country as a whole. *Id.* Moreover, FDA has broad discretion to fashion rulemaking procedures and remedies that best serve the public interest. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (FDCA "commit[s] complete discretion to [FDA] to decide how and when" its enforcement powers "should be exercised").[4]

Out of deference to Congress's intent and FDA's authority, courts have consistently held that state-law claims are impliedly preempted if "the existence of [the FDCA]" is "a critical element in [the plaintiff's] case," *Buckman*, 531 U.S. at 353, and adjudicating the claim would require a court "to decide whether, under the FDCA and its regulations," a violation has occurred, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 928 (9th Cir. 2010). In other words, private parties cannot use "state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA." *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290-91 (C.D. Cal. 2008). A state-law claim, therefore, is barred if it is "in substance (even if not in form) a claim for violating the FDCA." *Loreto v. Procter & Gamble*, 2013 U.S. App. LEXIS 3813, at *5 (6th Cir. Feb. 22, 2013).

[3] In limited circumstances not applicable here, States may sue to enforce certain provisions of the FDCA. 21 C.F.R. § 100.2. However, States must first notify FDA and give the Agency the opportunity to intervene. *See* FDA, *Final Rule: State Enforcement Provisions of the Nutritional Labeling and Education Act of 1990*, 58 Fed. Reg. 2457, 2460 (Jan. 6, 1993). States also may not seek to enforce the FDCA in any manner "inconsistent with FDA's interpretation of the Act." *Id.*

[4] The FDCA also expressly authorizes FDA to forgo prosecution of "minor violations . . . whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning." *Id.* § 336; *see also United States v. Sullivan*, 332 U.S. 689, 694 (1948) (FDA has authority *not* to redress "technical infractions of law").

3. Evaporated Cane Juice

a. FDA Has Not Determined Its Common and Usual Name

FDA has established formal "standards of identity" for a limited number of foods and beverages. If a food or beverage is one for which a standard of identity exists, it is "misbranded" under the FDCA unless the product is manufactured and labeled in accordance with FDA's standard. Most foods and beverages, however, do not have formal standards of identity. "Where no 'standard of identity' exists, [the FDCA] declares a food misbranded '[u]nless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common and usual name of each such ingredient[.]'" *Brod v. Sioux Honey Assoc.*, 2013 U.S. Dist. Lexis 27081, at *27 (N.D. Cal. Feb. 27, 2013); *see also* 21 C.F.R. § 101.4(a)(1) (requiring ingredients to be "listed by [their] common or usual name").

A common and usual name for a food or ingredient can be established in two ways. First, FDA may undertake formal notice-and-comment rulemaking and establish a common and usual name by regulation. 21 U.S.C. § 341. Second, and far more frequently, a food or ingredient acquires a common and usual name through "common usage" in the marketplace. 21 C.F.R. § 102.5(d). In either case, a common and usual name should describe in "simple and direct terms" the basic nature of a food or ingredient. *Id.*at § 102.5(a).

FDA has published regulations establishing standards of identity and/or common and usual names for several sweetening ingredients, including sugar, maple syrup, lactose, and cane syrup. *See* 21 C.F.R. §§ 101.4(b)(20) *et seq*. Many sweeteners, however, have not been defined by FDA regulation, and they have acquired common and usual names through widespread usage. Sweeteners for which no defining regulation exists include molasses, brown sugar, and ECJ.

b. FDA's Draft Guidance on Evaporated Cane Juice

ECJ is used in thousands of food and beverage products sold in the United States.[5] It is produced from sugar cane, but is not processed in the same manner as refined white sugar. The

[5] When FDA published the 2009 Draft Guidance, it was estimated that 3,500 to 9,000 products in the U.S. contained evaporated cane juice. (*See* RJN, Ex. A.)

name ECJ describes in "simple and direct" terms how the sweetener is made: juice is extracted from sugar cane, and the liquid is evaporated.

In 2009, FDA notified the public and industry that it was considering whether manufacturers should be required to use an alternative name for "evaporated cane juice" that better describes what it is. (*See* RJN, Ex. A.) FDA did not initiate formal notice-and-comment rulemaking or publish a proposed rule concerning ECJ. Rather, as the Agency often does before committing itself to a position, FDA issued a draft "Level 1" guidance document explaining that the Agency had concerns that the name "evaporated cane juice" may lead some consumers to think that products made with this ingredient contain actual "juice," which is not always the case. *Id.* The 2009 Draft Guidance suggested that "dried cane syrup" might be a more appropriate name. *Id.*

A draft Level 1 guidance is FDA's least formal means of notifying the public of its preliminary views on a topic. The purpose and legal status of Level 1 guidance documents are established by regulation, and set forth FDA's "initial interpretations" of statutory or regulatory requirements on "highly controversial issues." *See* 21 C.F.R. § 10.115(c). Because they are not legally binding or enforceable, FDA may publish draft Level 1 guidance documents without prior notice to the public or due process to affected parties. Accordingly, they are frequently used to initiate a dialogue with the Agency.[6]

Once a draft Level 1 guidance is published, members of the public, trade groups, and other stakeholders are invited to submit comments to FDA "at any time." *See id.* § 10.115(f)(4). Based on the feedback it receives, the Agency may publish the guidance as a proposed final rule, revise its preliminary position, or withdraw the draft guidance entirely. As the "draft"

[6] *See generally* FDA, Fact Sheet: FDA Good Guidance Practices, at http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285344.pdf (last visited May 29, 2013) ("Industry, consumers and other stakeholders play a significant role in the agency's guidance development processes… Draft proposals can help the agency better understand stakeholder positions, particularly if the subject involved deals with novel scientific issues… The agency also invites the public to comment on its draft Level 1 guidances and reviews and considers the submitted comments in preparing the final documents."). A copy of this FDA Fact Sheet is attached as Exhibit M to the accompanying RJN.

designation indicates, draft guidances are "documents that have been proposed, but FDA has not made a decision as to whether the proposal will be adopted in whole, in part or not at all."[7] Draft Level 1 guidance documents, in fact, are withdrawn with regularity.[8]

By law, a Level 1 guidance document cannot impose binding legal requirements because it has not been subjected to official rulemaking procedures. A "Q&A" that appears in the FDA's regulations makes this clear:

> Are you or FDA required to follow a guidance document?
>
> No. Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA.

Id. § 10.115(d). The 2009 Draft Guidance itself explains that "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities . . . . The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required." (*See* RJN, Ex. A.) In fact, FDA employees who treat a draft guidance document as a binding requirement are subject to disciplinary action, and manufacturers are instructed to contact the staff person's supervisor or the Agency's ombudsman should this occur. *See id.* § 10.115(o).

c. Warning Letters That Mention Evaporated Cane Juice

Even though FDA guidance documents are not binding or enforceable, FDA can—and often does—encourage manufacturers to comply with a draft guidance on a voluntary basis. One way FDA can usually obtain such voluntary compliance is by sending a "warning letter" to companies, threatening legal action unless they modify their labels. *See Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012) (explaining that warning letters are "the agency's principal means of achieving prompt voluntary compliance"). Even when FDA's

[7] *See* FDA, Proposed Regulations and Draft Guidances, at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm (last updated May 17, 2013). A copy of this page is attached as Exhibit L to the accompanying RJN.

[8] FDA maintains a list of active and withdrawn guidance documents on its website. *See* FDA, Guidances, at http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234622.htm (last updated Feb. 2, 2013).

position in a warning letter is factually inaccurate or legally suspect, recipients of warning letters often implement the changes FDA requests to avoid a public dispute with the Agency.

Since 2009, FDA has issued at least two warning letters that reference the 2009 Draft Guidance. (*See* RJN, Ex. J-K .) Neither letter was directed solely to the issue of ECJ. *Id.* In both cases, the warning letter cited the recipient for numerous, serious potential FDCA violations and mentioned ECJ in passing or near the end. *Id.*

FDA's decision to send warning letters over an issue covered by a draft Level 1 guidance does not change the legal status of the guidance or suggest that it is a binding requirement. In fact, warning letters themselves do "not necessarily represent the formal position of FDA, and [do] not bind or otherwise obligate or commit the agency to the view expressed." *See* 21 C.F.R. § 10.85(k). Like draft Level 1 guidance documents, warning letters are "informal" and "advisory." *Id.*; *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (FDA warning letters are not binding or final and "do not commit the FDA to enforcement action"); *Holistic Candlers*, 664 F.3d 940, 944-45 (D.C. Cir. 2012) (FDA warning letters "do not represent final agency action," bear no legal consequences, and "plainly do not mark the consummation of FDA's decision making"); *Dietary Supplemental Coalition, Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) (same); *Summit Tech. v. High-Line Med. Instruments, Co.*, 933 F. Supp. 918, 934 n. 9 (C.D. Cal. 1996) (same).

d. FDA's 2009 Draft Guidance Has Been Roundly Criticized

FDA has received public comments on its 2009 Draft Guidance from more than 50 companies, trade groups, and other stakeholders. All of the comments have criticized FDA's approach to ECJ for one or more reasons.

For instance, the Grocery Manufacturers Association (GMA), the leading trade association for food and beverage manufacturers, commented that the 2009 Draft Guidance is inconsistent with decades of industry practice. (*See* RJN, Ex. B.) Moreover, because ECJ is in fact the name commonly and usually used to identify this ingredient, GMA explained that the name ECJ necessarily complies with the FDCA. For these reasons, and in light of the high costs

of implementing the 2009 Draft Guidance, GMA urged FDA to scrap the guidance and completely rethink its approach.

Companies that make and sell ECJ also submitted comments to FDA. They noted that the replacement name for ECJ suggested by the 2009 Draft Guidance—"dried cane syrup"—is actually a *less* accurate name for this sweetener because there is no "syrup" phase in the production of ECJ. (*See* RJN, Ex. B-F.) Indeed, while three companies filed comments in support of FDA's desire to standardize the name for ECJ, even they recommended against finalizing the 2009 Draft Guidance as drafted—they each criticized some aspect of FDA's reasoning or recommendations. (*See* RJN, Ex. G-I.)

Since receiving public comments on the 2009 Draft Guidance, FDA has taken no steps to finalize its position. FDA has not issued a "final" guidance; it has not initiated formal notice-and-comment rulemaking; and it has not initiated a single enforcement action over ECJ, despite the fact that hundreds of products still list this sweetener as an ingredient on their labels.[9] Moreover, to this day, FDA's website cautions that the 2009 Draft Guidance only "Contains Nonbinding Recommendations," was "distributed for comment purposes only," and is "Not for Implementation." (*See* RJN, Ex. A.) Only "when finalized" will the guidance represent the FDA's "current thinking on this topic." *Id.* Until then, FDA expressly maintains that the 2009 Draft Guidance "does not create or confer any rights for or on any person." *Id.*

ARGUMENT

To avoid dismissal under Rule 12(b)(6), a plaintiff must plead facts sufficient to state a claim for relief that is plausible on its face. *See Davis v. Capitol Record, LLC*, 2013 U.S. Dist. LEXIS 55917, at *4 (N.D. Cal. April 18, 2013). While factual allegations must be taken as true,

[9] It is not unusual for a Level 1 document to remain in "draft" for months, if not years, before FDA decides whether to withdraw it or publish a binding final rule. But FDA is supposed to "periodically evaluat[e] draft guidance[s] to determine whether any guidance that has been in draft for more than three years should be withdrawn, finalized, or issued as a revised draft[.]" *See* FDA Report on Good Guidance Practices, at 3, http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf (last visited May 29, 2013). A copy of this FDA Report is attached as Exhibit N to the accompanying RJN.

"conclusory statements not supported by actual factual allegations need not be accepted," *id.*, and dismissal is warranted in the absence of a viable legal theory, *see Collings v. Teamsters Benefit Trust*, 2013 U.S. Dist. LEXIS 49752, at *5 (N.D. Cal. April 5, 2013).

Pursuant to Rule 12(f), a court may strike "redundant, immaterial, impertinent, or scandalous matter" from a complaint. Fed. R. Civ. P. 12(f). A motion to strike should be granted when "it is clear that the matter sought to be stricken could have no possible bearing on the subject matter of the litigation." *Kosta v. Del Monte Corp.*, 2013 U.S. Dist. LEXIS 69319, *11-12 (N.D. Cal. May 15, 2013) (citations omitted). Rule 12(f) allows a court to strike not only factual allegations, *see id.*, but also unsustainable class allegations, *see Sanders v. Apple, Inc.*, 672 F. Supp. 2d 978, 990 (N.D. Cal. 2009). In either case, the purpose of a Rule 12(f) motion is to "avoid the expenditure of time and money" required to litigate issues that are not properly in the case. *Kosta*, 2013 U.S. Dist. LEXIS 69319, at *11.

This Court and other courts in this District have considered motions to dismiss filed in numerous food "misbranding" cases. Notably, this case is different from others that have come before because Plaintiff alleges that Odwalla has violated the FDCA and California law for one reason only: the labeling of ECJ. As explained below, this issue is uniquely unsuited for resolution through private litigation under California law, and Plaintiff's claims are expressly and impliedly preempted. At a minimum, it is evident from the face of the Complaint that Plaintiff's nationwide class allegations are unsustainable.

I. CALIFORNIA LAW DOES NOT INCORPORATE NON-BINDING FDA GUIDANCE DOCUMENTS, SUCH AS THE ONE THAT PLAINTIFF SEEKS TO ENFORCE

The FDCA does not provide for private rights of action. Thus, Plaintiff has not asserted a claim under the FDCA directly, but bases her claims on California's Sherman Law, which purports to make the FDCA and its implementing regulations the law of that state. Like the FDCA, the Sherman Law also contains no private right of action, so Plaintiff has invoked California's consumer protection statutes, which prohibit, *inter alia*, conduct that is "unlawful"

under another statute or regulation. By cobbling together these various statutes, Plaintiff seeks to enforce the requirements of the 2009 Draft Guidance on ECJ against Odwalla.

California law does not permit this. According to its plain statutory text, the Sherman Law incorporates only binding FDA "food labeling ***regulations***" as "the food labeling regulations of this state." Cal. Health & Saf. Code § 110100; *see also In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1087 (Cal. 2008) ("California has adopted as its own the FDA regulations" regarding food labeling). The 2009 Draft Guidance on ECJ, however, is not a food labeling regulation. It is a non-final, non-binding draft "Level 1" guidance document, which, by law, does not create a legally enforceable obligation.

The California legislature clearly did not intend to make every draft FDA policy or preliminary position statement the law of the state. Indeed, since draft Level 1 guidance documents may be published by FDA without prior notice or public comment, it would raise serious Due Process concerns if California were to make them *automatically* binding under state law, potentially exposing companies that operate in that state to huge financial liability without warning. *See Louis v. United States Dept. of Labor*, 419 F.3d 970, 975 (9th Cir. 2005) (acknowledging that the notice-and-comment procedures for agency rulemaking are necessary to protect the Due Process rights of the regulated community). The Sherman Law avoids this constitutional concern by making only final, binding regulations the law in California.

In short, it would contradict the plain language of the Sherman Law to allow Plaintiff to enforce the 2009 Draft Guidance through California law. Plaintiffs' claims must be dismissed for this reason alone.

II. PLAINTIFF IS EXPRESSLY PREEMPTED FROM SEEKING TO IMPOSE REQUIREMENTS THAT FEDERAL LAW DOES NOT IMPOSE

As noted above, the NLEA's express preemption clause bars States from imposing any requirements that are "not identical" to specified categories of food labeling requirements under federal law. 21 U.S.C. § 343-1(a). Those preempted categories include requirements "of the type" in 21 U.S.C. § 343(i), which governs common and usual names. Moreover, state law is

"not identical" to federal law if it "differs" from the requirements of federal law in any respect, or imposes an obligation that federal law does not. *See* 21 C.F.R. § 100.1(c)(4); *see also Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011) ("Even if the disclaimers that the plaintiff wants added would be consistent" with the FDCA, "consistency is not the test; identity is.").

Plaintiff is seeking to do precisely what Congress has forbidden. Federal law does not require manufacturers to label ECJ by some other name, and FDA has so far chosen not to issue a binding regulation requiring products containing ECJ to be relabeled. Hundreds of manufacturers, in fact, continue to identify ECJ by that name on products sold in grocery stores throughout the country. As such, the NLEA's express preemption clause bars Plaintiff from seeking to impose, through her state-law claims, a requirement that Odwalla label ECJ by a different name. *See Carrea v. Dreyer's Grand Ice Cream, Inc.*, 475 F. App'x 113, 115 (9th Cir. 2012) (holding plaintiff was expressly preempted from imposing labeling requirements for trans fat that do not exist under federal law); *see also Perez v. Nidek Co.*, 711 F.3d 1109, 1118-19 (9th Cir. 2013) (finding claim expressly preempted because plaintiff "effectively [sought] to write in a new provision to the FDCA").[10]

Plaintiff undoubtedly will point out that one court in this District recently found that similar claims over the labeling for ECJ were not expressly preempted. *See Ivie v. Kraft Foods Global, Inc.*, 2013 U.S. Dist. LEXIS 25615 (N.D. Cal. Feb. 25, 2013). The preemption issues specific to ECJ, however, were not thoroughly briefed in that case, and the court's reasoning is not persuasive. The court concluded that the plaintiff's claims in that case were not preempted because the FDA's position on ECJ is "clear," and express preemption does not bar claims under the UCL's "deceptive" prong. *Id.* at *36. Neither conclusion is correct.

As discussed above, the 2009 Draft Guidance, in fact, does not even represent the FDA's official position or actual "thinking on this topic" until it is "finalized." (*See* RJN, Ex. A.)

[10] *See also Bronson v. Johnson & Johnson, Inc.*, 2013 U.S. Dist. LEXIS 54029 (N.D. Cal. April 16, 2013); *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1118-23 (N.D. Cal. 2010); *Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111, 1119-20 (C.D. Cal. 2010)

Moreover, in light of the dozens of critical comments FDA has received on the 2009 Draft Guidance, it is far from "clear" that FDA will finalize the guidance in its current form.

The *Ivie* court's apparent belief that plaintiffs can pursue claims under the "deceptive" prong of California's UCL without triggering preemption also was clearly incorrect. Regardless of the prong invoked by the plaintiff, courts have consistently held that plaintiffs' claims are expressly preempted when they would impose requirements that differ from federal law. *See Lam v. Gen Mills, Inc.*, 859 F. Supp. 2d 1097, 1101-03 (N.D. Cal. 2012) (finding claims expressly preempted where the "crux" of the Complaint was that defendants' labeling was deceptive); *Dvora v. Gen. Mills, Inc.*, 2011 U.S. Dist. LEXIS 55513, at *12-15 (C.D. Cal. May 16, 2011) (finding plaintiff's claims that "the phrase 'Naturally and Artificially Flavored' render[ed defendant's] product labeling both deceptive and non-compliant with federal regulations" preempted because they sought "to impose limitations . . . different from what federal regulations currently require/permit").

Plaintiff's claims, if successful, would require Odwalla to label ECJ by a different name. That requirement does not exist under federal law and, indeed, would depart significantly from current FDA requirements. Contrary to the court's holding in *Ivie*, such claims are squarely preempted by the NLEA's preemption clause.

III. PLAINTIFF CANNOT BASE HER CLAIMS ON THE GENERAL REQUIREMENT THAT INGREDIENTS BE IDENTIFIED BY THEIR COMMON AND USUAL NAMES

Plaintiff will likely attempt to circumvent the NLEA's preemption clause by arguing that, even putting aside the 2009 Draft Guidance, the FDCA includes a general requirement that all ingredients be labeled with an appropriate common and usual name, and that a private plaintiff can seek to enforce this "identical" requirement through California law. This argument should be rejected for multiple reasons.

A. General FDCA Requirements Cannot Trump FDA's Specific Approach to Evaporated Cane Juice

Foremost, if accepted, this argument would eviscerate the NLEA's express preemption clause. The FDCA, like many statutes, begins with several general provisions that broadly prohibit labeling that is "false or misleading" in any particular and require, *inter alia*, that foods be labeled with a common and usual name. These general provisions, however, are given specific meaning and effect through FDA's implementing regulations and final guidance documents. Once FDA has expressly considered how a general provision of the FDCA should be interpreted and applied in a specific context, and either has issued a regulation or has chosen not to impose a binding requirement, private plaintiffs are expressly preempted from second-guessing FDA's determination.

Not surprisingly, when plaintiffs have invoked the FDCA's general misbranding provisions in this manner, courts have consistently rejected this line of argument. For example, in *Gorenstein v. Ocean Spray Cranberries, Inc.*, 2010 U.S. Dist. LEXIS 143801 (C.D. Cal. Jan. 29, 2010), the plaintiff challenged the name and label of an Ocean Spray juice product and sought to impose disclosure requirements that FDA had previously considered and chosen not to implement. Notwithstanding FDA's prior determination, the plaintiff argued that his claims were not preempted because Ocean Spray's label violated the FDCA's *general* prohibition against "false or misleading" labels, and that he was entitled to enforce this "identical" requirement through his state-law claims. *Id.* at *1-2. The court rejected this argument, recognizing that such an interpretation "would eviscerate [the NLEA's] strict preemption requirements" and "defeat[] [its] statutory objective" that "federal law govern[] the content of [defendant's] label[s]" and that "manufacturers should not be subjected to 50 different sets of labeling rules." *Id.* at *3-5; *see also Red v. Kroger Co.*, 2010 U.S. Dist. LEXIS 115238, at *7-16 (N.D. Cal. Sept. 2, 2010) (rejecting plaintiff's argument that his claims were "beyond the NLEA's express pre-emption provision" because he premised liability on the FDCA's general misbranding provisions); *Chavez v. Nestle USA, Inc.*, 2011 U.S. Dist. LEXIS 9773, at *25 (C.D.

Cal. Jan. 10, 2011) ("Plaintiffs' argument that the 'False Or Misleading' language of 21 U.S.C. § 343(a) defeats express [NLEA] preemption is unpersuasive.").

Similar arguments have been squarely presented to the Ninth Circuit and rejected in an NLEA preemption case. In *Carrea v. Dreyer's Grand Ice Cream*, the plaintiff alleged that the defendant's ice cream labels violated California law because they stated that the product had "0 g of Trans Fat" when, in fact, small amounts of trans fat were present. The district court held that this claim was preempted because federal regulations expressly permit trans fat in amounts less than 0.5 grams per serving to be "expressed as zero." 2011 U.S. Dist. LEXIS 6371, at *8-12 (N.D. Cal. Jan. 10, 2011). On appeal, the plaintiff argued that, FDA's specific considerations notwithstanding, the FDCA prohibits labeling that is "false or misleading in any particular," and that his state-law claim merely sought to impose requirements "identical to [this] federal requirement[]."[11]

The Ninth Circuit affirmed the district court's dismissal order, agreeing that the plaintiff was preempted from seeking "to enjoin and declare unlawful" a labeling practice that "federal law permits." 475 F. App'x at 115. The Ninth Circuit apparently thought so little of the plaintiff's attempt to elevate the general language of the FDCA over FDA's specific regulations that it did not find it worthy of discussion in its opinion. But the court's holding necessarily rejects the argument.[12]

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[11] Reply Brief for Appellant at 9, No. 11-15263 (9th Cir. Oct. 28, 2011), 2011 U.S. 6th [sic] Cir. Briefs LEXIS 37, at *11-12; *see generally* Opening Brief for Appellant at 16-22, No. 11-15263 (9th Cir. July 29, 2011), 2011 U.S. 6th [sic] Cir. Briefs LEXIS 38, at *20-29; Reply Brief for Appellant at 3-10, No. 11-15263 (9th Cir. Oct. 28, 2011), 2011 U.S. 6th [sic] Cir. Briefs LEXIS 37, at *4-13.

[12] The Seventh Circuit rejected a similar argument in *Turek v. General Mills, Inc*. There, the plaintiff alleged that the labeling of Fiber One Chewy Bars was misleading because the product contained "non-natural" fiber and did not disclose that "non-natural" fiber is less beneficial that natural fiber. 754 F. Supp. 2d at 956-57. The district court dismissed the plaintiff's claims as preempted by the NLEA because FDA had specifically considered the purported differences between natural and "non-natural" fiber and had chosen not to require the type of disclosure that plaintiff sought. On appeal, the plaintiff invoked the FDCA's general prohibition against false and misleading labeling. See Reply Brief for Appellant at 4-5, No. 10-3267 (7th Cir. July 11, 2011). But the Seventh Circuit affirmed the dismissal of the plaintiff's claims, concluding that "[t]he disclaimers [about "non-natural" fiber] that the plaintiff wants added" to Fiber One labels "are not identical to the labeling requirements imposed on such products by federal law, and so they are barred." 662 F.3d at 427. Like the Ninth Circuit in *Carrea*, the Seventh

B. State-Law Claims That Seek to Short-Circuit FDA Procedures Are Impliedly Preempted

Plaintiff is also barred from enforcing the FDCA's general common and usual name requirement, or the parallel requirements of California law, to ban "evaporated cane juice" from food and beverage labels by the doctrine of implied preemption. Implied preemption is distinct from express preemption, and it serves a different purpose. Thus, even when a statute contains an express preemption clause, the existence of such a clause "does not bar the ordinary working of conflict pre-emption principles or impose a 'special burden' that would make it more difficult to establish [implied] preemption of laws falling outside the clause." *Arizona v. United States*, 132 S. Ct. 2492, 2505 (2012); *Buckman*, 531 U.S. at 352 (same); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-72 (2000) (same). Indeed, the Ninth Circuit recently reaffirmed that, notwithstanding the FDCA's express preemption provisions, the FDCA also impliedly preempts state-law claims in some circumstances. *See Perez v. Nidek Co.*, 711 F.3d at 1119-20.

This Court recently considered the issue of implied preemption under the FDCA in *Kosta v. Del Monte*, and rejected the argument advanced by the defendant in that case that *all* state-law claims that mirror FDCA requirements are impliedly preempted. 2013 U.S. Dist. LEXIS 69319, at *24-25 (N.D. Cal. May 15, 2013). The Court's holding in *Kosta*, however, should not preclude a finding of implied preemption in this case. To be clear, Odwalla is not arguing that California state-law claims premised on the Sherman Law *always* are impliedly preempted. Claims under state law, however, are (and must be) impliedly preempted when, as here, they would require the court or a jury to resolve a controversial question of statutory interpretation while FDA is still considering the very same issue.

A primary purpose of implied preemption is to prevent plaintiffs from short-circuiting FDA procedures, or circumventing the FDA process, through private litigation. Thus, whether or not the plaintiff's state-law claims "parallel," "mirror," or are "identical" to federal law, these claims cannot proceed if they would "interfere[] with the methods by which [a] federal

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Circuit did not dignify the plaintiff's "general-trumps-the-specific" argument with a response, but rejected it nonetheless.

regulatory scheme was designed to reach its goal," *Metrophones Telecomms., Inc. v. Global Crossing Telecomms., Inc.*, 423 F.3d 1056, 1073 (9th Cir. 2005) (citation omitted), or would "exert an extraneous pull on the scheme established by Congress." *Buckman*, 531 U.S. at 349.

Plaintiff's claims in this case would not just "interfere" or exert a "pull" on FDA procedures, they would circumvent them entirely and would conclusively decide an issue before FDA has done so. FDA has published regulations setting forth procedures for developing binding rules and authoritative, final guidance documents. Publication of a draft "Level 1" guidance document is, as its name indicates, only the first step in this process. It would thwart the entire purpose of FDA's deliberative process if Plaintiff were permitted to cut short the discussion, pre-judge the outcome, and enforce her preferred interpretation of the FDCA's common and usual name requirement.

The Ninth Circuit's decision in *PhotoMedex v. Irwin* is instructive. In that case, PhotoMedex asserted that a competitor, Ra Medical, was marketing a medical device that was "significantly" different from any previously FDA-approved device, and, therefore, Ra Medical's device should have been reviewed *de novo* and cleared by FDA before entering the U.S. market. 601 F.3d at 922.[13] PhotoMedex initially had complained to FDA that Ra Medical's device required separate approval and had "urg[ed]" FDA "to take . . . enforcement action," *id.* at 926 (emphasis omitted), but FDA had not done so, *id.* at 922, 928. PhotoMedex then sued Ra over its alleged FDCA violations, asserting claims under federal and California unfair competition laws.

The Ninth Circuit held that PhotoMedex's claims were barred, recognizing that adjudicating the claims would "require a court to usurp the FDA's prerogative to enforce the FDCA and to decide whether, under the FDCA and its regulations, [Ra's device] was" properly

[13] The *PhotoMedex* opinion referred chiefly to PhotoMedex's Lanham Act claim. However, the court's *holding* affirmed the dismissal of the UCL claim on the same grounds, 601 F.3d at 930-31 & n.7, and its reasoning depended heavily on Supreme Court precedent addressing implied preemption of state law, *id.* at 924 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)).

on the market. *Id*. at 928. PhotoMedex was "not permitted to circumvent" the FDA's established procedures and seek to "prove that [Ra] violated the FDCA" before FDA itself had completed its process and "reach[ed] that conclusion." *Id*. at 928. Rather, "the appropriate forum for PhotoMedex's complaints" was "the responsible regulatory agency"—that is, FDA. *Id*. at 929.

In the years since *PhotoMedex* was decided, the Ninth Circuit has repeatedly applied its holding to prevent private plaintiffs from asking a court to short-circuit FDA procedures and resolve contested policy issues before FDA has had a chance to do so. *See, e.g., POM Wonderful LLC v. Coca-Cola, Co.*, 679 F.3d 1170, 1175-76 (9th Cir. 2012) ("If the FDA believes" that the disputed juice "label misleads consumers, it can act. But [a] court [may not] act when the FDA has not."). Most recently, in *Perez v. Nidek Co.*, the Ninth Circuit held that a plaintiff's California state-law claims were impliedly preempted because, *inter alia*, they would have required a court to decide whether the defendant had violated the FDCA before FDA—which had sent the defendant a warning letter—had completed its investigation. 711 F.3d at 1119-20.

The Ninth Circuit's holdings in *PhotoMedex, Pom Wonderful*, and *Perez* are all applicable here. Congress has given FDA authority to interpret and enforce the FDCA's common and usual name provisions, and FDA has established draft guidance procedures that allow the Agency to obtain comments from the public and affected parties before committing to a final position. Although FDA has initiated the process to define a common and usual name for ECJ, and expressed a preliminary point of view, the Agency's process is ongoing. Plaintiff has no greater right than the plaintiffs in *PhotoMedex*, *Pom Wonderful*, or *Perez* to "bypass the FDA," *PhotoMedex*, 601 F.3d at 929, and ask a court find that Odwalla has violated a binding FDCA requirement where FDA has not established one.[14]

[14] Plaintiff will undoubtedly invoke the California Supreme Court's decision in *In re Farm Raised Salmon Cases*, which rejected an implied-preemption defense to a UCL action involving alleged violations of California's Sherman Law. 42 Cal. 4th 1077 (2008). But the facts of *In re Salmon* are distinguishable because the plaintiff was seeking to enforce a binding, final regulation regarding the disclosure of specific artificial colorants. In other words, Plaintiff was seeking to enforce through California law a requirement (a) that already existed under federal law, and (b) that FDA had specifically and definitely interpreted.

C. FDA Has Primary Jurisdiction To Decide This Issue

Even if Plaintiff's claims were not preempted (which they are), the Court nevertheless should decline to adjudicate whether ECJ is an acceptable common and usual name on primary jurisdiction grounds. Primary jurisdiction permits courts to dismiss "an otherwise cognizable claim" when, as here, it "implicates technical and policy questions" that a regulatory agency should resolve in the first instance. *See Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). The doctrine is necessary to prevent plaintiffs from ensnaring courts in matters within an Agency's jurisdiction, especially when a claim "requires resolution of an issue of first impression," *id.*, and "expertise or uniformity in administration," *Syntek Semiconductor Co., Ltd. v. Microchip Tech., Inc.*, 307 F.3d 775, 780, 781 (9th Cir. 2002).

Here, all of the factors relevant to primary jurisdiction weigh in favor of dismissal. Plaintiffs' claims would require the Court to resolve an issue that is squarely within FDA's jurisdiction. 21 C.F.R. § 10.25(b) (FDA has "primary jurisdiction" to make "the initial determination on issues within its statutory mandate."). This is an issue of first impression, and one that requires FDA's expertise and potentially impacts the labeling of thousands of products nationwide. *See Pom Wonderful*, 679 F.3d at 1178 (noting that courts "lack the FDA's expertise in guarding against deception in the context of [food and] beverage labeling"). Moreover, since FDA's draft guidance process concerning ECJ is still open and ongoing,[15] the Court should permit FDA to complete that process before entering the fray. *See Schering-Plough Healthcare Prods. Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508-10 (7th Cir. 2009) (Posner, J.) (affirming dismissal because the plaintiff "jumped the gun by suing before FDA addressed the misbranding

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Neither fact is true in this case. In any event, a California court's holding on an issue of federal law, such as preemption, is not binding on this Court, and the *In re Salmon* decision predates the Ninth Circuit's decisions in *PhotoMedex*, *Pom Wonderful*, and *Perez*.

[15] Courts in this district have declined to dismiss cases on primary jurisdiction grounds when FDA has affirmatively stated that it does not intend to regulate in the relevant area. *See, e.g., Jones v. ConAgra Foods, Inc.*, 2012 U.S. Dist. LEXIS 178352, *18 n. 4 (N.D. Cal. Dec. 17, 2012) ("[T]he FDA has shown no intention of setting out a national standard" for use of the term "natural".); *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1035 (N.D. Cal. 2009) ("[V]arious parties have repeatedly asked the FDA to adopt formal rulemaking to define the word natural and the FDA has declined to do so because it is not a priority and the FDA has limited resources."). Here, the exact opposite is true.

issue": FDA "should be given a chance to opine on the proper labeling" before a suit is filed because the Agency "has more experience with consumers' understanding of labels than judges"); *see also Gordon v. Church & Dwight*, 2010 U.S. Dist. LEXIS 32777, *5-6 (N.D. Cal. Apr. 2, 2010) (dismissing claims because FDA was considering public comments and data relevant to the question presented); *Taradejna v. General Mills*, 2012 U.S. Dist. LEXIS 174264 (D. Minn. Dec. 10, 2012) (dismissal appropriate where FDA had issued a proposed rule, but the rule was not yet final).

IV. PLAINTIFF CANNOT ASSERT CLAIMS ON BEHALF OF A NATIONWIDE CLASS

Although Plaintiff is a California resident and the Complaint asserts claims exclusively under California law, Plaintiff purports to bring this suit on behalf of all similarly situated purchasers of Odwalla products nationwide.[16] (Compl. ¶83.) Plaintiff's nationwide class allegations, however, should be stricken. California's consumer protection laws—and the privately enforceable Sherman Law in particular—are unique and materially different from the laws of other states, and the California Supreme Court has made clear that their reach does not extend beyond the state's borders.

The Ninth Circuit recognized in *Mazza v. American Honda Motor Co.*, 666 F.3d 581, 592-93 (9th Cir. 2012), that applying California's unique statutory consumer protection regime to purchases nationwide raises significant comity and Due Process concerns. Nationwide consumer class actions under California law, therefore, are generally inappropriate because they threaten to override other states' policy choices "in balancing" for themselves "the range of products and prices" available to state residents and "the legal protections afforded to them." *Id.* at 592; *see also Maniscalco v. Brother Int'l (USA) Corp.*, 709 F.3d 202, 209 (3d Cir. 2013) (refusing to permit a nationwide class under New Jersey law because applying one state's

[16] Perhaps recognizing that her nationwide class allegations are on *terra infirma*, Plaintiff seeks, in the alternative, to represent a sub-class of California purchasers.

consumer protection statute "to every potential out-of-state" transaction "would frustrate the policies of each" consumer's home state).

Of course, whether a case is suitable for class treatment is most often addressed at the class certification stage. But "[s]ometimes the issues are plain enough from the pleadings" to determine that the "class claims cannot be maintained." *See In re Clorox Consumers Litig.*, 894 F. Supp. 2d 1224, 1237 (N.D. Cal. 2012) (citing cases). In fact, courts in this District routinely grant motions to strike nationwide class allegations at the pleading stage, especially when differences between California and other states' laws would have a "material impact" on putative class members' claims. *Id.* at 1237; *see also Banks v. Nissan N. Am., Inc.*, 2012 U.S. Dist. LEXIS 37754 (N.D. Cal. Mar. 20, 2012) (striking nationwide class allegations because California UCL and CLRA cannot be applied to sales of vehicles to out-of-state consumers); *cf. Littlehale v. Hain Celestial Group, Inc.*, 2012 U.S. Dist. LEXIS 162530, *3-5 (N.D. Cal. July 2, 2012) (striking UCL, FAL and CLRA claims in light of "material differences" between California law other states' consumer protection statutes).

The comity and Due Process concerns that led the Ninth Circuit to reject the nationwide class in *Mazza* are "squarely implicated in this case." 666 F.3d at 593. Many states, in contrast to California, have chosen not to adopt the FDCA and FDA regulations *en masse* into state law.[17] Moreover, even in states that have adopted "mini-FDCA" acts in one form or another, state legislators have made a deliberate policy choice not to provide civil remedies to private plaintiffs. Most states, in fact, mandate that their "mini-FDCA" acts are enforceable only by government authorities with expertise in administering the statute. *See, e.g., Buckner v. Kentucky*, 2011 U.S. Dist. LEXIS 18476, at *6 (E.D. Ky. Feb. 24, 2011) (Kentucky's mini-FDCA act "does not create a private right of action," rather enforcement "is vested in the Cabinet for Health and Family Services and local prosecuting attorneys."); *Gentry v. Hershey Co.*, 687 F.

[17] For example, 28 states have not adopted provisions like California's that "incorporate" all FDA regulations. *See* FDA: State Operational Authority: State Authorities and Phone Contact Numbers, http://www.fda.gov/ICECI/Inspections/IOM/ucm122520.htm (last visited May 25, 2013). A copy of this page is attached as Exhibit O to the accompanying RJN.

Supp. 2d 711, 723 (M.D. Tenn. 2010) (Tennessee's FDCA can be enforced only by state Commissioner).

Plaintiff is undoubtedly aware that California law is materially different from the laws of other states, which explains why the Complaint asserts claims exclusively under California law. The California Supreme Court, however, has held that California's UCL has no application to transactions outside the state. *Sullivan v. Oracle Corp.*, 254 P.3d 237, 248 (Cal. 2011). As the court explained, "[n]either the language of the UCL nor its legislative history provides any basis for concluding the [state] Legislature intended the UCL to operate extraterritorially." *Id.* Plaintiff therefore is foreclosed from attempting to use California law to obscure or override the inherent diversity between the laws of every state. *See Koehler v. Litehouse, Inc.*, 2012 U.S. Dist. LEXIS 176971, *19 (N.D. Cal. Dec. 13, 2012) (recognizing that application of UCL and CLRA to non-California residents would "violate the presumption against the extraterritorial application of California laws and raises significant due process issues").

It is clear from the face of Plaintiff's Complaint that her claims arise solely under California law and are premised on a liability theory not recognized, or privately enforceable, in other states. In these circumstances, "each class member's consumer protection claim should be governed by the consumer protection laws of the jurisdiction in which the transaction took place," *Mazza*, 666 F.3d at 594, and Plaintiff's nationwide class allegations should be stricken.

V. PLAINTIFF'S ALLEGATIONS REGARDING FANTA ZERO ORANGE SODA SHOULD BE STRICKEN

Lastly, in addition to Odwalla beverages and bars, Plaintiff alleges that Coca-Cola's Fanta Zero Orange Soda is misbranded because it is labeled as containing ECJ. (Compl. ¶4.) Fanta Zero Orange Soda, however, does not contain ECJ, and its label makes no mention of ECJ. In fact, because it has zero calories, Fanta Zero Orange Soda contains no caloric sweetener of any kind. The Court may review the ingredients list on the Fanta Zero Orange Soda label for itself and confirm that Plaintiff's allegations regarding the labeling of this product are simply mistaken. (*See* RJN, Ex. T.) As this product has "no possible bearing on the subject matter of

this litigation," references to it in the Complaint should be stricken. *Kosta*, 2013 U.S. Dist. LEXIS 69319, at *11.

CONCLUSION

For all of the forgoing reasons, Plaintiff's Complaint should be dismissed, in its entirety, with prejudice. In the alternative, the nationwide class allegations and references to Fanta Zero Orange Soda should be stricken from the Complaint.

DATE: June 3, 2013

Respectfully submitted,

PATTERSON BELKNAP WEBB & TYLER LLP
/s/ Steven A. Zalesin
Steven A. Zalesin (admitted *pro hac vice*)
Travis J. Tu (admitted *pro hac vice*)
1133 Avenue of the Americas
New York, New York 10036
Phone: (212) 336-2000
Fax: (212) 336-2222

Gary T. Lafayette
LAFAYETTE & KUMAGAI LLP
100 Spear Street, Ste. 600
San Francisco, California 94105
Phone: (415) 357-4600
Fax: (415) 357-4605

Attorneys for Defendants